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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,766	03/03/2004	Michelle M. Hanna	2072.0010008/LBB/SJE	4955
26111	7590	11/21/2007	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			KIM, YOUNG J	
		ART UNIT	PAPER NUMBER	
		1637		
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		11/21/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,766	HANNA, MICHELLE M.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 136-174 is/are pending in the application.
- 4a) Of the above claim(s) 138,143,157-161 and 163-170 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 136,137,139-142,144-156,162 and 171-174 is/are rejected.
- 7) Claim(s) 147 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The present Office Action is responsive to the Amendment received on August 27, 2007.

Preliminary Remark

Claims 1-135 are canceled.

Claim 174 is new.

Claims 138, 143, 157-161, and 163-170 remain withdrawn as being drawn to non-elected invention, non-elected with traverse in the Response received on September 25, 2006.

Claim Objections – Necessitated by Amendment

Claim 147 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 147 recites that a linker comprises a single-stranded overhang region of 5 to about 40 nucleotides.

Claim 142, which serves as a parent to claim 147 has been amended to recite that the linker comprises a single-stranded overhang region of 5 to 40 nucleotides (without the term, “about”).

Hence, claim 147 which adds the term, “about” before the limitation, “40 nucleotides” clearly broadens the metes and bounds of the parent claim.

Claim Rejections - 35 USC § 112

The rejection of claims 136, 137, 139-142, 144-156, 162, and 171-173 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter, made in the Office Action mailed on November 1, 2006 is withdrawn in view of the Amendment received on August 27, 2007.

Rejections, New Grounds – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 137 and 149 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 137 is indefinite for reciting species of target-specific linkers which are not nucleic acids. It is pointed out that claim 136 which serves as a parent claim for 137 has been amended to require that the target specific linker is a “nucleic acid.” Hence, it is unclear what is meant when claim 137 recites that that a nucleic acid linker is, for example, an antibody.

Claim 149 is amended to recite the phrase, “said oligonucleotide.”

Parent claim 136 recites several oligonucleotides (i.e., upper and lower oligonucleotides, two complementary oligonucleotides). It is unclear to which oligonucleotide, the “said” oligonucleotide is referring to.

Claim 173 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection.

Applicants have amended the parent claim 136 to require that the target specific linker be nucleic acid. Claim 174, which depends from claim 136, requires that the molecule defined by claim 136 comprise 2, 3, or 4 target specific nucleic acid linkers. It is respectfully submitted that a cursory review of the instant specification did not reveal a literal support for such an amendment.

Applicants are requested to specifically point out where in the specification the support could be found or remove the new matter.

Claim Rejections - 35 USC § 102

The rejection of claims 136, 137, 139-142, 144-146, 151-155, 171, and 172 under 35 U.S.C. 102(b) as being anticipated by Munroe et al. (U.S. Patent No. 5,597,694, issued January 28, 1997), made in the Office Action mailed on November 1, 2006 is withdrawn in view of the Amendment received on August 27, 2007. In particular, the prior art does not teach a target specific linker which comprises a single-stranded overhang region of 5 to 40 nucleotides.

The rejection of claims 136, 137, 139-142, 144-147, 151-156, 171, and 172 under 35 U.S.C. 102(b) as being anticipated by Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2¹; herein, Daube 2), made in the Office Action mailed on November 1, 2006 is withdrawn in view of the Amendment received on August 27, 2007. In particular, none of the prior arts teach a target specific linker which comprises a single-stranded overhang region of 5 to 40 nucleotides.

Rejection, New Grounds – Necessitated by Amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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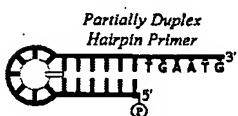
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 136, 137, 149, 150, and 171 are rejected under 35 U.S.C. 102(e) as being anticipated by Cantor et al. (U.S. Patent No. 6,660,229 B2, issued December 9, 2003, filed Jun 13, 2001).

Cantor et al. disclose a synthetic molecule comprising a self-complementary DNA sequence comprising a self-complementary sequence which is made from one contiguous oligonucleotide, and a target-specific linker on at least the 3' or 5' end of one strand, wherein said target-specific linker is a nucleic acid linker comprising a single-stranded overhang region of 5 to 40 nucleotides (see Figure 4, see element (a)).



Structurally, the molecule disclosed by Cantor et al. meets all of the limitations imposed by claims 136 and 137, embodiment (a)(i).

With regard to claims 149 and 150, the primer is disclosed as being 5 to 200 nucleotides (column 10, lines 65-66).

With regard to claim 171, the overhang appears on the 3' end of the construct (Figure 1(a)).

Therefore, Cantor et al. anticipate the invention as claimed.

¹ IDS received on December 20, 2004.

Claims 136, 137, 139-141, 149, 150, 171, and 174 are rejected under 35 U.S.C. 102(b) as being anticipated by Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993).

Berninger et al. disclose a proto-promoter construct comprising a self-complementary DNA sequence and an RNA-binding site, wherein said self-complementary sequence is made of one contiguous oligonucleotide to which RNA polymerase can bind, and having a 3' overhang that comprises 5 to 40 nucleotides (see Figure 1, and Figure 4), clearly anticipating claims 136, 171, and 174.

With regard to claim 137, the overhang is made of DNA sequences.

With regard to claims 139-141, the proto-promoter comprises a transcription promoter sequence (column 7, lines 26-27).

With regard to claim 149 and 150, the proto-promoter construct can comprise 8 base pair overhang, with 22 nucleotide pairs long duplex region, which results in the structure being 52 nucleotides (column 7, lines 50-60).

Therefore, Berninger et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The rejection of claims 136, 137, 139-142, 144-148, 151-156, and 171-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2¹; herein, Daube 2) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993), made in the Office Action mailed on November 1, 2006 is withdrawn in view of the Amendment received on August 27, 2007. In particular, none of the prior arts teach a target specific linker which comprises a single-stranded overhang region of 5 to 40 nucleotides.

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The rejection of claim 162 under 35 U.S.C. 103(a) as being unpatentable over Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2¹; herein, Daube 2) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993) as applied to claims 136, 137, 139-142, 144-148, 151-156, and 171-173 above, and further in view of Kim et al. (U.S. Patent No. 5,846,723, issued December 8, 1998), made in the Office Action mailed on November 1, 2006 is withdrawn in view of the Amendment received on August 27, 2007. In particular, none of the prior arts teach a target specific linker which comprises a single-stranded overhang region of 5 to 40 nucleotides.

New, Necessitated by Amendment

Claims 136, 137, 139-142, 144-156, 171, 172, and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munroe et al. (U.S. Patent No. 5,597,694, issued January 28, 1997) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993).

The instant rejection is based on the fact that the claims are drawn to a product. So long as the prior art disclosure meets all of the limitations set forth in the product claims, said claims are anticipated and discovery of new property or use of previously known composition, even if unobvious from prior art, cannot impart patentability to claims to known composition (*In re Spada*, 15 USPQ2d 1655, 911 F2d 705, August 10, 1990).

Munroe et al. disclose a molecule comprising a two partially complementary upper and lower oligonucleotides that form a single-stranded transcription bubble region comprising a defined site (see Figure 1, “Bubble Oligos”; column 2, lines 52-60) and a linker on at least 3’ or 5’ end of its strand (bubble complex is specifically ligated to its target sequences which are digested with blunt

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cutting restriction enzymes; *see* column 2, lines 50-51 and 58), thereby clearly anticipating claims 136 137, 139-142, 171, and 172.

With regard to claims 144 and 146, Munroe et al. disclose that the complementary regions of the bubble complex which flank the single-stranded region, comprise approximately 10 to approximately 50 complementary nucleotides (column 2, lines 53-55).

With regard to claim 145, Munroe et al. disclose that the single-stranded region of the bubble complex comprises approximately 15 to approximately 35 nucleotides (column 2, lines 55-57).

With regard to claims 151-155, the bubble complex is disclosed as being ligated to phage clone (column 2, lines 49), or nucleic acid specific to disease, disorder, or condition such as fragile x syndrome, acute myelocytic leukemia, and solid tumors (column 11, lines 60-67).

Munroe et al. do not disclose the their bubble complex comprise an overhang.

Berninger et al. disclose a proto-promoter construct comprising a self-complementary DNA sequence and an RNA-binding site, wherein said self-complementary sequence is made of one contiguous oligonucleotide to which RNA polymerase can bind, and having a 3' overhang that comprises 5 to 40 nucleotides (see Figure 1, and Figure 4), wherein said overhang is made of DNA sequences.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Munroe et al. with the teachings of Berninger et al., thereby arriving at the claimed invention for the following reasons.

While the bubble oligonucleotide of Munroe et al. was ligated to the target nucleic acid via blunt end ligation, one of ordinary skill in the art at the time the invention was made would have recognized that there are other means of ligating an adaptor structure to a target nucleic acid, such as that of an overhang.

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Berninger et al. clearly demonstrates that an adaptor structure comprising an overhang comprising over 5 nucleotides can be ligated to the target nucleic acid for the further nucleic acid processing.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success at combining other means of ligating an adaptor structure to a target nucleic acid, such as an overhang, arriving at the invention as claimed.

Given the fact that one of ordinary skill in the art would have been motivated to employ the complex of Berninger et al., one of ordinary skill in the art would have had a reasonable expectation of success at designing any target specific linker so long as there was motivation to amplify a target sequence.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 151-156 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993) in view of Kim et al. (U.S. Patent No. 5,846,723, issued December 8, 1998).

The teachings of Berninger et al. have already been discussed above.

Berninger et al. do not explicitly disclose that their method be employed in methods of diagnosis of various conditions.

Berninger et al. do not explicitly disclose that the linker be specific for a telomerase.

Kim et al. disclose a well known practice for detecting telomerase activities for the purposes of detecting malignant cancers (column 1, lines 34-37).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the method disclosed by Berninger et al. thereby arriving at the claimed

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invention because by doing so, one of ordinary skill in the art would have been capable of characterizing the nucleic acids associated with various conditions.

Lastly, with regard to the linkers being specific for a telomerase, one of ordinary skill in the art would have been motivated to combine the teachings of Berninger et al. with the teachings of Kim et al., thereby arriving at a molecule comprising a target specific linker for telomerase, because by doing so, one of ordinary skill in the art would have been capable of detecting, diagnosing, or monitoring cancer in a sample. Given the fact that one of ordinary skill in the art would have been motivated to employ the complex of Berninger et al., one of ordinary skill in the art would have had a reasonable expectation of success at designing any target specific linker so long as there was motivation to amplify a target sequence.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claim 162 is rejected under 35 U.S.C. 103(a) as being unpatentable over Munroe et al. (U.S. Patent No. 5,597,694, issued January 28, 1997) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993), as applied to claims 136, 137, 139-142, 144-156, 171, 172, and 174 above, and further in view of Kim et al. (U.S. Patent No. 5,846,723, issued December 8, 1998).

The teachings of Munroe et al. and Berninger et al. have already been discussed above.

Neither Munroe et al. nor Berninger et al. explicitly disclose that the linker be specific for a telomerase.

Kim et al. disclose a well known practice for detecting telomerase activities for the purposes of detecting malignant cancers (column 1, lines 34-37).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the method disclosed by Munroe et al. and Berninger et al. thereby

arriving at the claimed invention because by doing so, one of ordinary skill in the art would have been capable of characterizing the nucleic acids associated with various conditions.

Lastly, with regard to the linkers being specific for a telomerase, one of ordinary skill in the art would have been motivated to combine the teachings of Munroe et al. and Berninger et al. with the teachings of Kim et al., thereby arriving at a molecule comprising a target specific linker for telomerase, because by doing so, one of ordinary skill in the art would have been capable of detecting, diagnosing, or monitoring cancer in a sample. Given the fact that one of ordinary skill in the art would have been motivated to employ the complex of Munroe et al. and Berninger et al., one of ordinary skill in the art would have had a reasonable expectation of success at designing any target specific linker so long as there was motivation to amplify a target sequence.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 136, 137, 139-142, 144-148, 151-156, 162, 171-173 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-31 and 35-43 of copending Application No. 10/976,240 (herein, '240 application), made in the Office Action mailed on November 1, 2006 is maintained for the reasons already of record.

Applicants' request to have the rejection be held in abeyance is noted.

Until a properly filed Terminal Disclaimer is filed, the rejection will be maintained for the reasons already of record.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims of '240 application is drawn to a narrower species of the generic construct as claimed in the instant application, and thus renders the instant claims obvious in a genus-species reasoning. While claims 23-31 of '240 application recites a generic term, "abortive promoter cassette," in view of the Figures of '240 application referencing an abortive promoter cassette, the constructs are identical to the construct defined in the instant application, and therefore, deemed obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

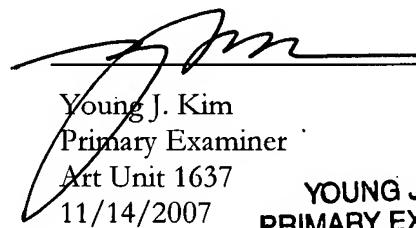
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent

to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Young J. Kim
Primary Examiner
Art Unit 1637
11/14/2007

YOUNG J. KIM
PRIMARY EXAMINER

YJK